JUL 2 5 2000

Special 510(k) Summary – Device and Material Modifications
Summary of Safety and Effectiveness for the
MRH Tibial Rotating Component

Proprietary Name:	Modular Rotating Hinge Knee Tibial Rotating Component
Common Name:	Tibial Component
Classification Name and Reference:	Knee joint femorotibial metal/ polymer, constrained cemented prosthesis 21 CFR §888.3510
Proposed Regulatory Class:	Class II
Device Product Code:	OR (87) KRO
For Information contact:	Jennifer A. Daudelin, Regulatory Affairs Howmedica Osteonics Corp. 359 Veterans Boulevard Rutherford, NJ 07070-2584 (201) 507-7283 Fax: (201) 507-6870

This Special 510(k) submission is intended to address a design and material modification to the Modular Rotating Hinge (MRH) Tibial Rotating Component. The manufacturing methods, intended use, packaging and sterilization of the subject device are identical to those of predicate device. The predicate tibial rotating components can be assembled with any Howmedica Osteonics Modular Rotating Knee Femoral component. The tibial rotating components are available in two sizes, extra-small-extra large and large-extra large. The large-extra large component has a 3mm posterior offset to offer the surgeon greater options. Both the predicate device and the subject device will be provided sterile. The predicate device was found substantially equivalent via the 510(k) process. The material modification involves adding an alternate material for this device. The predicate device is currently fabricated from cast Vitallium® (CoCr) Alloy which complies with ASTM Standard F75. The subject device will be fabricated from the above referenced material and an alternate material of forged Vitallium® (CoCr) Alloy that conforms to ASTM F799.

The modified component will also incorporate slight design changes to accommodate manufacturability of the forgings. The subject forged component modifies the width across the knuckle from 19mm below the circular pads to 20mm to maintain a constant width of 20mm

along the entire length of the knuckle. Additionally, the "pad" under the bumper will extend to the posterior edge of the component.

The intended use of the modified device, as described in its labeling, has not changed as a result of this modification. These devices are intended to be implanted with bone cement for the following condition(s): destruction of the joint surfaces with or without significant bone deformity; the cruciate and/or collateral ligaments do not stabilize the knee joint; and/ or the ligaments are inadequate and/or the musculature is weak.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2000

Ms. Jennifer A. Daudelin
Regulatory Affairs
Howmedica Osteonics Corp.
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

Re: K001957
Trade Name: Modular Rotating Hinge Knee Tibial Rotating Component
Regulatory Class: II
Product Code: KRO
Dated: June 26, 2000
Received: June 27, 2000

Dear Ms. Daudelin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Vochmer

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K001957

Device Name: MRH Tibial Rotating Component

Indications for Use:

The Modular Rotating Hinge Knee System is intended to be implanted with bone cement for the following condition(s): destruction of the joint surfaces with or without significant bone deformity; the cruciate and/or collateral ligaments do not stabilize the knee joint; and/ or the ligaments are inadequate and/or the musculature is weak.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Donna R. Bachmann
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001957